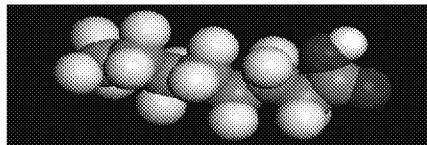


**EPA's Lifetime Drinking Water  
Health Advisories (HA) for  
Perfluorooctane Sulfonate (PFOS)  
and Perfluorooctanoic Acid (PFOA)**

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# Background-Chemical Characteristics

- PFOS and PFOA are two chemicals in a large group (hundreds) of manmade chemicals called perfluoroalkyl substances (PFAS).
- PFAS have many uses, including as surfactants and to make products more resistant to stains, grease, and water.
- PFOS and PFOA both have 8 carbon atoms and are resistant to biodegradation, photolysis and hydrolysis.
- PFOS and PFOA are the terminal degradation products formed from longer chain commercial, biodegradable precursors.
- Both chemicals have similar environmental fate and transport processes.
  - They are stable in the environment, including in water.
  - Low volatility, but adsorb to airborne particulates and can be transported long-range.
  - Mobile in water and soils.
  - Bioaccumulate across trophic levels.



# Background-Physiological Behavior

- Both chemicals are very persistent in the human body.
  - PFOA half-life in blood serum: 2.3 years (general population)
  - PFOS half-life in blood serum: 5.4 years (occupational exposure)
- Six CDC National Health and Nutrition Examination Surveys (NHANES) analyzed PFAS in blood serum between 1999 and 2012.
  - PFOA and PFOS were detected in 99.7% and 99.9% of the U.S. population.
  - Serum concentrations declined over this period:
    - PFOA (geometric mean) concentration from 5.2 µg/L to 2.12 µg/L.
    - PFOS (geometric mean) concentration from 30.4 µg/L to 6.31 µg/L.

## Previous and Current Uses: Industrial and Consumer Products

### PFOA

- ✧ Cooking surfaces (Teflon)
- ✧ Aqueous film forming foams (used in fire fighting)
- ✧ Toothpaste, Shampoos, cosmetics
- ✧ Polishes and waxes
- ✧ Electronics
- ✧ Lubricants/surfactants/emulsifiers
- ✧ Pesticide
- ✧ Plumbing Tape
- ✧ Food containers and contact paper
- ✧ Textiles (Gore-Tex) and Leather
- ✧ Paints, varnishes, sealants
- ✧ Cleaning products
- ✧ And more...

### PFOS

- ✧ Metal plating and finishing
- ✧ Fire fighting foams
- ✧ Photograph Development
- ✧ Semiconductor industry
- ✧ Aviation Fluids
- ✧ Flame repellants
- ✧ Packaging Papers
- ✧ Oil and Mining
- ✧ Stain repellants on carpets and upholstery (e.g. Stainmaster, ScotchGard)
- ✧ Cleaning products
- ✧ Paints, varnishes, sealants
- ✧ Leathers, textiles
- ✧ And more...

Pesticide use cancelled 2008

Food packaging (pizza boxes, microwave popcorn, sandwich bags, fast food wrapping papers, etc) cancelled January 2016

# Environmental Occurrence Examples

- Manufacturing sites
  - DuPont, Diakin, 3M, Ashai, Clariant, etc.
- Industrial use sites
  - Dispersion processors including Saint-Gobain sites (Hoosick Falls)
  - Glass/Cloth Coating
  - Manufacturing and Formulating Coating Products
  - Metal Coating
  - Additives
  - Film and Film Coating Manufacturing
  - Impregnated Felt Cloth
  - Fluoropolymer Fiber Production
- Industrial and municipal waste sites
  - Landfills
  - Waste water treatment plants (Industrial and Municipal)
  - Land application of biosolids
- Fire/crash training areas
  - FAA airports
  - Federal Facilities

# U.S. Production

- PFOS and PFOA are the two PFAS that have been produced in the largest amounts in the U.S since 1950.
  - Both PFOA and PFOS have been phased out of production in the U.S. and replaced by shorter chain PFAS or other compounds.
    - In 2000-2002, PFOS was voluntarily phased out of production in the U.S. by its primary manufacturer, 3M. EPA has issued regulations to require notification before any new future manufacturing, including importation of PFOS and its precursors. A limited set of existing uses are not subject to these regulations because they were ongoing at the time of the regulation.
    - In 2010, eight companies entered into a voluntary agreement to phase out production of PFOA and longer chain chemicals that degrade to PFOA by the end of 2015. There are notice requirements for use on imported carpets and some specialty uses are ongoing.
  - Production is still ongoing in other countries, and thus, importation of products containing both compounds is possible.
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# Process for Development of Lifetime HAs

## ■ 2014 Public Panel Peer Review

- Followed EPA's 2013 *Conflict of Interest Review Process for Contractor-Managed Peer Reviews of EPA HISA and ISI Documents*.
  - Three Federal Register Notices: 1) released draft documents for 60-day public comment period and solicited panel nominations, 2) published interim list of panel members for public comment, and 3) announced final panel and meeting details.
- Panel included experts with expertise in epidemiology, toxicology (liver, immune, neurological and reproductive and developmental effects, risk assessment, pharmacokinetic modeling, and mode-of-action.
- Public comments on the draft documents were provided to the panel prior to the panel meeting in August 2014.

## Summary of Health Effects

- PFOA and PFOS health effects information is available from animal studies and human epidemiology studies.
- Studies indicate that PFOA and PFOS exposure results in multiple health effects including: developmental effects, effects on serum lipids and total cholesterol, liver and kidney effects, immune effects, reproductive effects, and cancer.
- Animal studies were used quantitatively to develop candidate non cancer reference doses (RfDs).
  - Human epidemiology studies were used as additional supporting lines of evidence.
- Under EPA's Cancer Guidelines there is *Suggestive* evidence of carcinogenic potential for both PFOA and PFOS.
  - PFOA-Positive association for kidney and testicular cancers from epidemiology literature and liver, testicular, and pancreatic tumors in rats.
  - PFOS-No positive associations from epidemiology literature and evidence of liver adenomas and thyroid in rats (lacked dose-response).

## Reference Dose (RfD) Selection

- EPA modeled average serum values using a peer-reviewed pharmacokinetic model (rat, mouse, and monkey) developed by ORD.
  - **PFOA:** 6 studies for effects on development (delayed ossification and accelerated puberty, pup body weight; adult body and kidney weight); liver; and immune system.
  - **PFOS:** 6 studies for effects on development (pup body weight, neurodevelopment, pup survival) and liver.
- For both PFOA and PFOS, the RfDs based on multiple adverse effects resulting from short-term and longer-term exposures fall within a narrow range.
- EPA selected the most sensitive RfD based on developmental effects to calculate a health advisory protective for the general population and sensitive lifestages.

# Critical Studies Selected as Basis for RfDs

## ■ PFOA

- Lau et al., 2006
  - ※ Developmental toxicity study
  - ※ Dosing throughout pregnancy gestational days 1-17; pups sacrificed at weaning (e.g., lactational exposure included)
- Decreased ossification in proximal phalanges and accelerated puberty in male pups
- RfD derived from a lowest observed adverse effect level (LOAEL) and a total uncertainty factor of 300
  
- **RfD = 0.00002 mg/kg/d**

## ■ PFOS

- Luebker et al., 2005b
  - ※ 2-generation reproductive toxicity study
  - ※ Dosing pre-mating and throughout pregnancy and lactation for 2 generations
- Decreased body weight and weight gain in pups
- RfD derived from a no observed adverse effect level (NOAEL) and a total uncertainty factor of 30
  
- **RfD = 0.00002 mg/kg/d**

## Lifetime HA Calculation for PFOA and PFOS

$$\text{Lifetime HA} = \frac{\text{RfD} \times \text{RSC}}{\text{DWI/BW}}$$

Where:

HA = Health Advisory

RfD = Reference Dose [0.00002 mg/kg/d]

RSC = Relative Source Contribution [20% ]

DWI/ BW = DWI adjusted by BW for lactating women [0.054 L/kg]

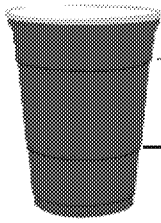
$$\text{Lifetime HA} = \frac{0.00002 \text{ mg/kg/d} \times 0.2}{0.054 \text{ L/kg}}$$

$$\text{Lifetime HA} = 0.00007 \text{ mg/L}$$

$$= 0.07 \text{ } \mu\text{g/L or 70 parts per trillion (ppt)}$$

Due to the potential increased susceptibility during the time period of pregnancy and lactation, EPA used drinking water intake and body weight parameters for lactating women in the calculation of a Lifetime HA for this target population during this potential critical time period. EPA used the rate of 54 mL/kg-day representing the consumers only estimate of combined direct and indirect community water ingestion at the 90th percentile for lactating women (see Table 3-81 in U.S EPA, 2011). Comparing between the pregnant and lactating woman, the lactating woman is the most sensitive given her increased water intake rate (54 mg/L-day) to support milk production. Additionally, human studies have shown that PFOA and PFOS are transferred from mother to infant via cord blood and breast milk. A recent study showed that breast milk contributed > 94% and > 83% of the total PFOS and PFOA exposure, respectively, in 6-month-old infants (Haug et al., 2011).

## Relative Source Contribution (RSC)



RSC of 80%-Exposure is primarily from drinking water; reserve 20% of RfD to account for exposure through other sources (e.g., dust, air, soil, etc.)

RSC of 20%-Exposure is primarily through other sources (e.g., dust, air, soil, etc.); reserve 20% of RfD to account for exposure via drinking water.

- EPA derived an **RSC of 20% for PFOA and PFOS** for the national HA based on available occurrence information and considering the environmental persistence of these compounds
  - CDC data provide evidence of broad exposure to PFAS from multiple sources.
  - Currently, diet is the major source of PFOA and PFOS:
    - Food products including fish, snack foods, vegetables grown in contaminated soils, and meat and dairy products from exposed grazing animals
    - Food packaging products and use of Teflon cookware
  - Contaminated drinking water
  - Indoor dust is another major source (especially to children) from treated carpets and furniture/textiles in homes, offices, automobiles.
  - Other sources of legacy exposure or exposure to precursors: soils, air, clothing, cosmetics, cleaning materials, etc.

# Lifetime HA and Application

- The Lifetime HAs are based on developmental effects resulting from exposures that occur during pregnancy and lactation (nursing) and are protective for all other health effects (non-cancer and cancer) that may occur during a lifetime of exposure to these chemicals in drinking water.
- Because the critical effects identified are developmental effects and can potentially result from a short-term exposure during a critical period of development, the Lifetime HAs apply to both short term (weeks to months), such as the time periods during pregnancy and nursing and bottle feeding, as well as chronic (lifetime) exposure scenarios.
- Because the toxicological effects of PFOA and PFOS are very similar, where these chemicals co-occur in drinking water at the same time, we recommend that the HA be applied to the sum of the concentrations of PFOA and PFOS.
  - EPA has not evaluated the toxicity of other PFAS at this time.

- EPA Office of Water PFOA and PFOS  
website: <https://www.epa.gov/ground-water-and-drinking-water/drinking-water-health-advisories-pfoa-and-pfos>
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